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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,413	08/27/2003	Axel Ullrich	224160	5257
23460	7590	01/13/2006	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			SHAVER, SHULAMITH H	
		ART UNIT	PAPER NUMBER	1647

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/649,413	ULLRICH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 August 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1-14, drawn to a method of treatment of an RTK-hyperfunction disorder, classification dependent upon recited compound.
- II. Claim(s) 15 and 16 in part, drawn to a method of diagnosis of an RTK-hyperfunction disorder by determining presence of a mutated protein, classified in class 435, subclass 7.1.
- III. Claim(s) 15 and 16 in part, 17-19, drawn to a method of diagnosis of an RTK-hyperfunction disorder by determining presence of nucleic acid encoding a mutated protein, classified in class 435, subclass 6.
- IV. Claim(s) 20-22, drawn to method of identifying inhibitor of mutant FGFR-4, classified in class 435, subclass 7.1.
- V. Claim(s) 23-25, drawn to method for treatment of RTK-hyperfunction-induced disorder by administering an inhibitor of a mutant FGFR-4, classification dependent upon recited compound.
- VI. Claim(s) 26-29, drawn to antibodies, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods of Inventions I-V appear to constitute five patentably distinct inventions for the following reasons: Groups I and V are directed to treatment methods. These methods have different steps, require different reagents and have different goals and outcome measures than the methods recited in Inventions II and III which are drawn to diagnostic methods. All four of these

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methods require search for, and identification of an appropriate patient population, which is not required for the methods of Invention IV, which is drawn to a method of identifying an inhibitor of mutant FGFR-4. The search for all these inventions is not co-extensive and would place an undue burden on the examiner and the USPTO resources.

Inventions I and V are both directed to treatment methods. However, Invention V recites a method of treatment comprising administration of an inhibitor of a mutant FGFR-4. A search for the methods of Invention V would require an extension of the search for the methods of Invention VI. The search for these two inventions is not co-extensive.

Inventions II and III are both drawn to diagnostic methods. However, Invention II is drawn to a method of diagnosis comprising detecting a protein; Invention III recites a method of diagnosis comprising detecting a nucleic acid. These two methods have different steps, require different reagents and have different goals and outcome measures. The search for these two inventions is not co-extensive.

Inventions I-V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention VI are not made or utilized by any of the methods of Inventions I-V.

Because all these Inventions are distinct for the reasons given above, have divergent subject matter and the searches for the six inventions are not co-extensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ELIZABETH KEMMERER  
PRIMARY EXAMINER

SHS